

APR - 3 2012

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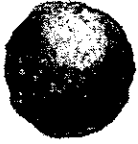
510(k) SUMMARY

- 1. Applicant Name and Address** CooperVision, Inc.
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588 USA
(925) 621-2450
- 2. Contact** Karin Gastineau
Director, Global Regulatory Affairs
CooperVision, Inc.
(925) 621-3732
- Date Prepared** Original: December 20, 2012
Revised: January 19, 2012
- 3. Device Identification** Common Name: Soft Contact Lens
Trade Name: AVAIRA (*enfilcon A*) Soft Contact Lens
Class Name: Soft (hydrophilic) Contact Lens, Daily Wear (Disposable)
Classification: Class II [21 CFR 886.5925]
Product Code: LPL, MVN

4. Device Description

The AVAIRA (*enfilcon A*) soft contact lens is a daily wear silicone hydrogel contact lens that is not surface treated and is characterized by high oxygen permeability (Dk). The lens material, *enfilcon A*, is composed of silicone macromers cross linked with other monomers, incorporating phthalocyanine blue as an integrated, handling tint. A UV blocker is added to reduce the amount of ultraviolet light transmitted into the eye. The lens will be manufactured in spherical, aspherical, toric and multifocal configurations with the following features and properties:

• Chord Diameter	• 13.5 mm to 15.0 mm
• Center Thickness	• 0.05 mm to 0.60 mm
• Base Curve	• 8.2 mm to 9.2 mm
• Power Range	• -20.00D to +20.00D in 0.25 steps
• Cylinder Power (TORIC)	• -0.25 to -10.00 D
• Add Power (Multifocal)	• +0.50 to +4.00 D
• Refractive Index (hydrated)	• 1.40
• Water Content	• 46% by weight in normal saline
• Oxygen permeability	• $100 \times 10^{-11} [(cm^2/sec)(ml O_2)/(ml \cdot mmHg)]$, 34°C, Polarographic method (corrected)



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The lens is supplied sterile in blister packs containing a buffered saline solution. Labeling is printed with appropriate lot numbering, expiration dating and lens parameter identification. Expiration dating is established based on studies of product stability, package integrity, and sterility.

5. Intended Use

SPHERICAL AND ASPHERICAL:

AVAIRA (*enfilcon A*) Sphere and Asphere soft contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

TORIC:

AVAIRA (*enfilcon A*) Toric soft contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

MULTIFOCAL:

AVAIRA (*enfilcon A*) MULTIFOCAL soft contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

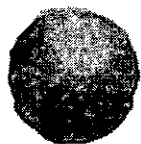
The AVAIRA (*enfilcon A*) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. When prescribed for planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting systems. The lens may also be prescribed for single-use disposable daily wear.

6. Predicate Device(s)

- ◆ COOPERVISION AQUAIR (*enfilcon A*) Soft Contact Lens [K071736]

7. Characteristics of Substantial Equivalence

The AVAIRA (*enfilcon A*) Soft Contact Lens is substantially equivalent to the COOPERVISION AQUAIR (*enfilcon A*) Soft Contact Lenses. The lenses are low water, nonionic, silicone hydrogel lenses. The lenses are Class II and have indications for daily wear per premarket notification. The following Table summarizes the primary features for this comparison, illustrating the similarities and differences.



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Attributes	CooperVision AVAIRA [Current Submission]	CooperVision AQUAIR [K071736]
Material	<i>enfilcon A</i> silicone hydrogel	<i>enfilcon A</i> silicone hydrogel
Category (Group)	N/A (low water, nonionic)	N/A (low water, nonionic)
Manufacturing Method	Cast Molded	Cast Molded
Indication	Daily Wear	Daily Wear
Water Content (%)	46	46
Oxygen Permeability - Dk @ 35°C [(cm ² /sec) x (ml O ₂)/(ml x mm Hg)]	100 x 10 ⁻¹¹ †	100 x 10 ⁻¹¹ †
Refractive Index	1.40	1.40
Light Transmittance (%)	> 97	> 97
Chord Diameter Range(mm)	13.5 to 15.0	13.5 to 15.0
Base Curve Range (mm)	8.2 to 9.2	8.2 to 9.2
Center Thickness (mm)	0.08 @ -3.00D	0.08 @ -3.00D
Powers	-20.00D to +20.00D in 0.25 steps	-20.00D to +20.00D in 0.25 steps

† polarographic method (corrected) ‡ coulometric method

8. Physical and Optical Studies

The physical and optical properties of the lenses as assessed by various test methods show substantial equivalency with the predicate device as illustrated in the preceding table. Additional studies were conducted to verify that leachable substances were either low or below measurable levels to mitigate any concerns for its intended use.

9. Biocompatibility Studies

Biocompatibility studies were conducted and verified that AVAIRA (*enfilcon A*) lenses were biocompatible for the intended use as assessed using ISO 10993 standards for ocular irritation, cytotoxicity, and systemic toxicity. All results passed with no evidence of adverse clinical effects caused by the modified *enfilcon A* lens.

10. Human Clinical Studies

Clinical studies were conducted on the predicate device to demonstrate substantial equivalence of the *enfilcon A* lens as compared with historical data of the COOPERVISION BIOFINTY lens based on performance and safety. No additional clinical study was required for the modified *enfilcon A* lens.



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11. Conclusions

The *enfilcon A* soft contact lens with the modified process has the same intended use and substantially similar indications, technological characteristics, and principles of operation as the cleared *enfilcon A* soft contact lens ("predicate device"). The minor differences between the device and the predicate device do not raise any new questions of safety or effectiveness. The testing conducted demonstrates that the device meets design inputs and is substantially equivalent to the predicate. Thus, the modified *enfilcon A* soft contact lens is substantially equivalent to its predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ms. Karin J. Gastineau
Director, Global Regulatory Affairs
CooperVision, Inc.
6150 Stoneridge Mall Road, Suite 370
Pleasanton, CA 94588

APR - 3 2012

Re: K113759
Trade/Device Name: AVAIRA (enfilcon A) Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: March 2, 2012
Received: March 5, 2012

Dear Ms. Gastineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

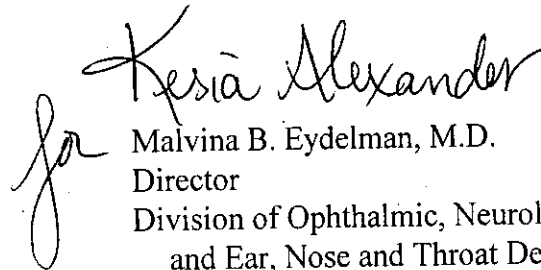
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Kesia Alexander" with a large, stylized "for" written to the left of the main signature.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: AVAIRA (*enfilcon A*) Soft (Hydrophilic) Contact Lens**Indications for Use:****SPHERICAL AND ASPHERICAL:**

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MULTIFOCAL:

AVAIRA (*enfilcon A*) Multifocal lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The AVAIRA (*enfilcon A*) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. When prescribed for planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting system. The lens may also be prescribed for single-use disposable daily wear.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Optional Format 1-2-96)


(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113759